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10/801,342

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Hyun Jin Hwang

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JHK Law

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EXAMINER

PANDE, SUCHIRA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/801,342

Applicant(s)

HWANG ET AL.

Examiner

Suchira Pande

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14, 16, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/31/06; 5/6/06</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group II invention claims 8-14, 16 and 19-20 in the reply filed on August 23, 2006 is acknowledged. The traversal is on the ground(s) that the applicant feels it is unlikely that their apparatus will be used as a temperature block. This is not found persuasive because the issue is whether distinct uses exist. Since there are obvious possible uses, the groups remain distinct. The criteria applied by Examiner in the restriction requirement to show distinctness between apparatus and process claims is valid. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 1-7, 15 and 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention of Group I, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 23, 2006.

***Response to Amendment***

3. Amendments to the specifications filed on August 23, 2006 intended to correct the translation errors from Korean to English are acknowledged and entered.

***Specification***

4. The amendment filed on August 23, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added

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material which is not supported by the original disclosure is as follows: Replacement paragraph [0064] adds text "located at an upper portion of the sample" that was not present in the original application. This is not correcting any translation error.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Priority***

5. The current application is being examined for art purposes using the priority of date in international PCT/KR02/01728 application filed on September 14, 2002. No English translations of the Foreign Priority, Korean applications have been provided by the applicants.

***Claim Objections***

6. Claims 9-10 and 12 are objected to because of the following informalities: From the last part of the claim where "or a combination of the heating unit and the cooling unit is claimed" it appears as if the applicant wants to claim either a heating unit or a cooling unit in the second part of the claim. If this is the intent then the claim should read "-----; and a heating unit----- conductive solid, or a cooling unit -----." The conjunction "or" is missing from the claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 8-9 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunicke-Smith WO 97/48818 published 24 December 1997 (cited by applicant in the IDS) in view of Benett et. al. WO 02/072267 A1 filed 22 February 2002 with US priority date of 9 March 2001 (cited by applicant in the IDS).

A) Regarding claim 8, Hunicke-Smith teaches :

*A nucleic acid sequence amplification apparatus using PCR* (see page 2, lines 5-6 where Hunicke-Smith teaches an apparatus for thermally cycling a DNA sample (another name used in the art for PCR is taught),

*which apparatus comprises: a plurality of heat sources* (see page 2, lines 6-7 where Hunicke-Smith teaches first and second heating elements)

*which may supply heat to* (see page 2, lines 7-12, where Hunicke-Smith teaches the heating chambers that contact the capillary tube containing sample),

*or remove heat from* (see page 3, lines 6-7, where Hunicke-Smith teaches a heating unit assembly further containing a cooling element that can remove heat from sample contained in reaction vessel (capillary in this case)).

Hunicke-Smith teaches selected first and second elevated temperature (page 2, lines 11-12).

Hunicke-Smith teaches "*wherein the specific temperature distribution fulfilling a temperature condition suitable for (i) a denaturation step in which double strand DNAs become separated to single strand DNAs, (see page 2, lines 14-15, where Hunicke-Smith teaches temperature that is effective to denature the DNA sample) (ii) an annealing step in which the single strand DNAs formed in the denaturation step hybridize to the primers to form DNA-primer complexes, or (iii) a polymerization step in which the primers in the DNA-primer complexes are extended by the polymerization reaction* (see page 2, lines 15-16, where Hunicke-Smith teaches second temperature at which DNA annealing and primer directed DNA polymerization can occur).

Regarding claim 19, Hunicke-Smith teaches: *wherein the plurality of heat sources* (see page 2 lines 7-9, where first and second heating elements defining first and second heating chambers are taught) *comprises a first thermally conductive solid that is in contact with a lower portion of the reaction vessel and a second thermally conductive solid that is in contact with an upper portion of the reaction vessel.* (see Fig. 1A and page 7, lines 27-32 where heating unit assemblies are taught. Each heating unit assembly contains at least two heating elements, such as first heating element 24 that is in contact with a lower portion of reaction vessel (capillary) and a second heating

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element 26 that is in contact with an upper portion of the reaction vessel (capillary). The desired temperature in these heating elements is maintained by utilizing independently controlled heating elements, such as elements 24 and 26 using power transistors in integrated chips and microprocessors (see page 8, lines 13- 24). It is well known in the art that transistors and microprocessors on integrated chips are solids and the fact elements 24 and 26 serve as heating elements indicates they are de facto conductive solids. Thus Hunicke-Smith teaches thermally conductive solids.

Regarding claim 20, Hunicke-Smith teaches: *The nucleic acid sequence amplification apparatus of claim 19, wherein the plurality of the heat sources further comprises a third thermally conductive solid that is in thermal contact with an intermediate portion of the reaction vessel in between the upper and lower portion.* (see page 14, lines 4-10, where 3 separate heating chambers, formed by 3 separate heating elements and preferably containing 3 separate temperature sensors-one for each heating element are taught. They teach that the third chamber of each assembly provides a third temperature zone through which the DNA sample may be cycled thus accomplishing 3 temperature PCR employing a denaturing temperature (high temperature), an annealing temperature (low temperature) and an extension (intermediate temperature). It should be noted that Hunicke-Smith does not explicitly state that the third thermally conductive solid is in thermal contact with an intermediate portion of the reaction vessel in between the upper and lower portion. Fig. 5 shows 3 heating elements 110, 112, 114. But no reference is made about spatial temperature

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distribution ie. intermediate temperature is the portion between the upper and lower portion.

B) Regarding claim 8 Hunicke-Smith does not teach spatial temperature distribution therefore following elements related to spatial temperature distribution in the claim are not taught by Hunicke-Smith: *a plurality of specific regions in a sample contained in a reaction vessel, wherein the heat sources are arranged to maintain a specific spatial temperature distribution in the sample such that a relatively high temperature region is located lower in height than a relatively low temperature region.*

*, and wherein the specific spatial temperature distribution is a temperature distribution that induces circulation of the sample by thermal convection so that the denaturation, annealing, and polymerization steps occur sequentially and repeatedly inside the sample”.*

C) Regarding claim 8, Bennett et. al. teach:

*a plurality of specific regions in a sample contained in a reaction vessel (see Fig. 3 where Bennett et. al. teach two sample regions marked 13 and 14 in a reaction vessel), wherein the heat sources are arranged to maintain a specific spatial temperature distribution in the sample such that a relatively high temperature region is located lower in height than a relatively low temperature region (see page 5, lines 20-23 where Bennett et. al. teach a relatively high temperature region called the “Upper Temperature Zone 13” located lower in height than a relatively low temperature region called “Lower Temperature Zone 14”. Bennett et. al. teach that by heating specific sections a convection cell is created thereby necessarily teaching that the heat sources*



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are arranged to maintain a specific spatial temperature distribution in the sample such that a relatively high temperature region Zone 13 is located lower in height than a relatively low temperature region Zone 14.

In view of above teaching it is necessary that the intermediate temperature zone required for PCR extension will be located in between the upper low temperature zone 14 and lower high temperature zone 13. Therefore clear description of spatial localization of high temperature zone to bottom and low temperature zone to top provides support to the conclusion that the intermediate temperature zone and the third heating element recited in claim 20 and taught by Hunicke –Smith is actually located in a region in between the upper and lower portion.

Regarding claim 9, Benett et. al. teach *wherein at least one of the heat sources comprises a thermally conductive solid in thermal contact with a specific region of the reaction vessel or the sample* (see page 5 line 23 where Benett et. al teach thermally conductive solid such as platinum heater as a heat source that is in contact with zone 13 of the reaction vessel; also see page 8, lines 11-14).

It would have been *prima facie* obvious to one of ordinary skill in the art to combine the structural elements taught by Benett et. al. in the PCR apparatus taught by Hunicke-Smith. The motivation to do so is provided by Benett et. al. who teach the inefficiency associated with the conventional PCR machines where heating and cooling of material other than the PCR sample itself. They state "There is an increasing need to build smaller more portable PCR systems for use in the field and clinical settings.---- This embodiment of the present invention provides a convectively driven PCR thermal-

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cycling system 10" (see Benett et. al. page 5, lines 7-14). Thus by combining the structural elements taught by Hunicke –Smith with the elements taught by Benett et. al. one would get a more efficient PCR apparatus that is capable of convective circulation thereby eliminating the cumbersome and contamination prone plunger system of moving the samples of Hunicke-Smith within the reaction vessel. Further Benett et. al. point out that their system is also amenable to miniaturization as is intended by the applicant.

10. Claims 10-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunicke-Smith and Benett et. al. as applied to claims 8-9 and 19-20 above, and further in view of Haff et. al. US.Pat. 5,720,923 issued February 24, 1998.

Regarding claims 9-12, Hunicke-Smith and Benett et. al. teach the PCR apparatus of claim 8 but do not specifically teach thermally conductive solid, liquid or gas as heat sources.

Regarding claim 9, Haff et. al. teach *at least one of the heat sources comprises a thermally conductive solid in thermal contact with a specific region of the reaction vessel or the sample; and a heating unit that supplies heat to the thermally conductive solid* (see col. 3, lines 66-67 and col 4, lines 1-3 where Haff et. al. teach two metal blocks each of which has its temperature stabilized at one of two temperatures (denaturation and anneal/extend incubation) needed for PCR that are in thermal contact with the sample in the reaction vessel (capillary tube)). Thus Haff et. al. teach heat sources that are thermally conductive solid (metal blocks) in thermal contact with reaction vessel. By

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teaching blocks stabilized at temperatures required for PCR, a heating unit that supplies heat to these metal blocks is taught by Haff et. al.

Regarding claims 10-11, Haff et. al. teach *wherein at least one of the heat source comprises a liquid in thermal contact with a specific region of the reaction vessel; a receptor in which the liquid is to be contained; and a heating unit that supplies heat to the liquid and wherein at least one of the heat sources further comprises a circulation unit that circulates the liquid around the reaction vessel.* (see col. 3, lines 45-54 where Haff et. al. teach use of two or three temperature stable fluid baths, each of which is constantly circulating its fluid through a separate conduit. Each fluid bath is thermostatted at one of the necessary PCR incubation temperatures (this teaching implies that the liquid in the bath is being heated by a heating unit and perhaps there is also a cooling unit that is helping to maintain the temperature required by the thermostat) this liquid of the fluid bath is in thermal contact with capillary (reaction vessel) containing the reaction mixture.)

Regarding claim 12, Haff et. al. teach *at least one of the heat sources comprises a gas in thermal contact with the reaction vessel; a heating unit that supplies heat to the gas and a circulation unit that circulates the gas around the reaction vessel.* (see col. 2, lines 10-19, where an oven with a heating coil (source of heat), a solenoid activated door and a fan (to circulate gas) are taught. Here Air was used as the heat transfer medium. The samples in capillary tubes are placed in this oven). Thus Haff et. al. teach gas in thermal contact with the reaction vessel; a heating unit that supplies heat to the gas and a circulation unit that circulates the gas around the reaction vessel.

Regarding claim 14, Haff et. al. teach *which method uses a means for insulating heat transfer between the heating sources.*( see col. 7, lines 30-33 and Fig.1 where high temperature bath 16 and low temperature bath 18 are separated by a layer of insulation 20 which is selected to minimize the flow of heat between the two baths 16 and 18. Also see col. 15, lines 54-58 where layer of insulation 174 separating metal block heat exchangers 170 and 72 are taught).

It would be *prima facie* obvious to one of ordinary skill in the art to combine the structural elements of the PCR apparatus taught by Haff et. al. in the PCR apparatus taught by Hunicke-Smith and Benett et. al. The motivation to do so is provided by Haff et. al. because not only does Haff et. al. teach solid, liquid and gas sources of heat each of them having their own advantages as system of heat transfer but they also teach use of insulation between different heat sources as a means of insulating heat transfer between heating sources. In addition they teach use of Peltier device to control temperature of the metal blocks (see col. 16, lines 12-14). Thereby allowing each heat source to efficiently maintain the desired temperature.

11. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunicke-Smith and Benett et. al. as applied to claims 8-9 and 19-20 above, and further in view of Northup WO 98/25701 published 18 June 1998 (cited by applicant in the IDS).

Regarding claims 12-13 Hunicke-Smith and Benett et. al. teach the PCR apparatus of claim 8 but do not teach thermally conducting gas as one of the heat sources.

Regarding claims 12, Northup teaches *at least one of the heat sources comprises a gas in thermal contact with a specific region of the reaction vessel; a heating unit that supplies heat to the gas; and a circulation unit that circulates the gas around the reaction vessel.* (see bottom of page 3 and page 4, line 1; where Northup teaches use of forced air heater to heat the tubes). By this teaching Northup teaches a gas as a heat source that is in thermal contact with reaction vessel and a circulation unit (forced air system) that circulates the gas around the reaction vessel.

Regarding claims 13, Northup teaches *wherein at least one of the heat sources is an infrared radiation generating unit that supplies heat directly to the sample* (see page 12, last 3 lines in bottom of page, where Northup teaches use of Infra Red (IR) source and Fig.3. where IR source 17 applies heat to solution in chamber 31.

It would be *prima facie* obvious to one of ordinary skill in the art to combine the structural elements of the PCR apparatus taught by Northup in the PCR apparatus taught by Hunicke-Smith and Benett et. al. The motivation to do so is provided by Northup who teach advantages associated with integrated microfabricated reactor developed for in situ chemical reactions, which is especially advantageous for biochemical reactions which require high precision thermal cycling, particularly DNA-base manipulations such as PCR, since small dimensions of microinstrumentation promote rapid cycling times (see page 4, par. 1).

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunicke-Smith and Benett et. al. as applied to claims 8-9 and 19-20 above, and further in view of Macho et. al. US Pat. No. 5,919,622 issued July 6, 1999 (cited by applicant in the IDS).

Regarding claim 16, Hunicke-Smith and Benett et. al. teach the PCR apparatus of claim 8 but do not teach wherein heat source is shaped to comprise at least one protrusion that fits in an opening of the reaction vessel, wherein said protrusion contacts the sample.

Regarding claim 16, Macho et. al. teaches *wherein the heat source is shaped to comprise at least one protrusion that fits in an opening of the reaction vessel, wherein said protrusion contacts the sample* (see col. 5, lines 14-25 where Macho et. al. teach a heat source that dips into the vessel in a manner that the liquid receives an adequate amount of heat. Also see Fig. 1. where protrusion 5 is shown to fit in an opening of the reaction vessel through stopper 3 with a lid 1 attached to it).

It would be *prima facie* obvious to one of ordinary skill in the art to combine the structural elements of the PCR apparatus taught by Macho et. al. in the PCR apparatus taught by Hunicke-Smith and Benett et. al. The motivation to do so is provided by Macho et. al. who state "The subject of the invention is a system for the temperature adjustment treatment of nucleic acid containing liquids in a vessel which has a reusable thermostat element and a disposable heating element, whereby heating element is a integral part of the vessel or the vessel lid and is dipped into the liquid during the treatment" see col. 2. lines 12-17. Also see col. 10 lines 63-64 where Macho et. al. teach a heating element where the resistance wire extended about two thirds of the way into the PCR mix. Besides providing a source of heat, such a disposable arrangement also provides a means to selectively introduce a component such as polymerase into the reaction to start the reaction.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 8, 16 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 8 of copending Application No. 10/836,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because the PCR apparatus described in claims 7 and 8 of copending application make the PCR apparatus claimed in claims 8, 16 and 20 of the instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***


Thus all claims 8-14, 16 and 19-20 under consideration are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande  
Examiner  
Art Unit 1637

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
